REMARKS

Upon entry of the present amendment, claims 1-9 and 56-60 will be pending. Claims 1-9 and 56-59 stand rejected. Claim 4 has been amended to clarify that the non-porous or semi-porous material controls the direction of flow of the composition from the high porosity tip. The amendment to claim 4 is fully supported by the instant specification as filed, for example, at page 12, last three lines. Claim 8 has been amended to specify that the high-porosity tip of that claim is biocompatible *and* resorbable; such amendment is fully supported by the instant specification as filed, for example, at page 13 and claims as filed. New claim 60 has been added and is fully supported by the instant specification as filed, for example, at page 12. No new matter has been added.

Applicants acknowledge and appreciate the withdrawal of the rejection of claims 1-9 and 56-59 for alleged obviousness over U.S. Pat. No. 7,081,122 to Reiley ("the Reiley patent") in view of U.S. Pat. No. 6,671,561 to Moaddeb ("the Moaddeb patent").

Rejections Under 35 U.S.C. § 103(a)

Claims 1-2, 9, and 56-59 have been rejected for alleged obviousness over the Reiley patent in view of U.S. Pub. No. 2001/0025157 to Kriesell ("the Kriesell publication"). According to the Office, the present claims are allegedly rendered obvious by the fact that one skilled in the art would have recognized that the tip of the catheter of the Reiley patent could be modified to provide a "porous delivery tip 66 that has a multiplicity of fluid passageways 66a" as taught by the Kriesell publication (*see, e.g.,* paragraph [0086]). Applicants respectfully disagree, at least because the posited combination is not one that a skilled artisan would have been motivated to make, and even if there existed sufficient motivation (a point that the Applicants do not necessarily concede), the resulting combination would not result in any claimed invention.

The Reiley patent provides a tool system for accessing interior bone spaces and delivering into such spaces restorative materials such as bone cement, bone matrix, or bone graft materials (*see e.g.*, Reiley patent at col. 11, lines 4-45). The restorative material is delivered to the bony space from a cannula (or from a "nozzle" that is passed through the

cannula) having a distal end that is situated at the site of treatment (*Id.* at col. 10, lines 1-41). According to the Reiley patent, "[t]he flow of material 138 into the [bone] cavity 134 . . . serves to uniformly distribute and compact the [restorative] material 138 inside the cavity 134" (*Id.* at col. 10, lines 21-25). In other words, the mechanism for introducing restorative material that is taught by the Reiley patent is said to provide satisfactorily uniform distribution of the material into the site of treatment. Although the Office suggests that one skilled in the art would have looked to the Kriesell publication in order to provide a tip that "permit[s] the medicinal fluid to flow uniformly outward of the tip" (4/9/08 Office Action at paragraph bridging pages 2-3), one skilled in the art would recognize that the Reiley patent itself already teaches that the cannula and optional nozzle apparatus provides satisfactorily uniform flow outward of the tip of the disclosed delivery system, and would not believe that modification of the tool system described by the Reiley patent with the tip described by the Kriesell patent would be necessary or effective to enhance any function of the tool system. Accordingly, the sole rationale presented by the Office as to why it would have allegedly been obvious to one skilled in the art to modify the tip of the catheter of the Reiley patent by providing a "porous delivery tip" as disclosed by the Kriesell publication is undermined by the teachings of the primary reference.

Furthermore, one skilled in the art would not have believed that the "porous delivery tip" disclosed by the Kriesell publication would be suitable for use with the tool system of the Reiley patent. In fact, from the respective teachings of the cited prior art, one skilled in the art would believe that modifying the tool system of the Reiley patent in the proposed manner would render the tool system unsatisfactory for its intended purpose. The Kriesell publication is said to be directed to a "small-volume, low flow rate fluid dispensing device for dispensing medicinal fluids" at "ultra low controlled flow rates over very long periods of time" (Kriesell publication at Abstract & paragraphs [0007]-[0008]). The dispensing device is implanted into a patient's body, where the heat of the patient's body causes a heat expandable mass to controllably expand, which in turn moves a plunger that expels a medicament out of the device and into the site of implantation (*Id.* at paragraphs [0057]-[0061], [0078]-[0079]). The "porous delivery tip" of the Kriesell publication is therefore adapted for use in connection with the delivery of a "small volume" of medicament at an "ultra low controlled flow rate". In clear contrast, the tool system of the Reiley patent

requires the ability to dispense comparatively large volumes of bone restorative material (for example, adequate quantities of material to fill an intraosseous space) in a sufficiently brief period of time as to minimize the duration of the invasive surgical procedure (*see, e.g.,* Reiley patent at col. 1, lines 30-34), for example, to avoid subjecting the patient to an unduly long invasive process, and/or to avoid the hardening of a bone cement restorative material before it can be completely dispensed. Accordingly, given the respective teachings of the Kriesel publication and the Reiley patent, one skilled in the art would not believe that a tip that is adapted for delivery of a small volume at an ultra low controlled flow rate over very long periods of time would be suitable for use with the system disclosed by the Reiley patent, concerning which the ability to deliver comparatively large volumes in as brief a period of time as possible are vital characteristics. Indeed, providing such a tip to the tool system of the Reiley patent would have been thought by one skilled in the art to render the tool system unsatisfactory for its intended purpose, and as such a *prima facie* case of obviousness cannot be said to exist.

Even if there existed sufficient motivation to modify the tool system of the Reiley patent with a "porous delivery tip" as disclosed by the Kriesell publication (a point that the Applicants do not necessarily concede), the resulting combination would not result in any claimed invention. Claim 1 and its dependents (including rejected claims 2, 9, and 56-59) are directed to a kit including a catheter with a substantially rigid tip that has a porosity of about 60% to about 90%. There is no evidence of record, and indeed the Office does not allege, that the "porous delivery tip" of the Kriesell publication has a porosity that falls within the presently claimed range. Indeed, the fact that the Kriesell publication is said to be directed to a "small-volume, low flow rate fluid dispensing device for dispensing medicinal fluids" at "ultra low controlled flow rates over very long periods of time" (Kriesell publication at Abstract & paragraphs [0007]-[0008]) strongly suggests that the "porous delivery tip" could not possess a high degree of porosity, because high porosity would be incompatible with delivering a fluid at the requisite "ultra low" rate over the prescribed "very long" period of time – *i.e.*, the inclusion of a tip having 60%-90% porosity could interfere with the device's ability to satisfactorily control the release of a fluid medicament. In any event, there is no evidence that the Kriesell publication teaches or suggests a tip having about 60% to about 90% porosity, and as such, a *prima facie* case of obviousness has not been presented. *In re*

Royka, 490 F.2d 981 (C.C.P.A. 1974) (to establish a prima facie case of obviousness, all claim limitations must be taught or suggested by the prior art). For at least this reason as well, the rejection of claims 1-2, 9, and 56-59 under § 103(a) should be withdrawn.

Claims 3-8 have been rejected for alleged obviousness over the Reiley patent in view of the Kriesell publication and in further view of U.S. Pat. No. 6,671,561 to Moaddeb ("the Moaddeb patent"). The Office has contended that although the Reiley patent and the Kriesell publication fail to disclose a porous tip having any of the materials or characteristics recited in claims 3-8, one skilled in the art would have allegedly looked to the Moaddeb patent to provide porous tips falling within the scope of the rejected claims. Applicants respectfully disagree, at least because the Office's conclusion is not based on any particular findings that one skilled in the art would have selected the cited references for combination, and furthermore, even if one skilled in the art would have been motivated to combine the cited references, the resulting combination would not result in any claimed invention.

The cited references cannot fairly be said to render Applicants' claimed inventions obvious because there is no evidence of record demonstrating that those of ordinary skill in the art would have been motivated to actually combine the references' respective teachings or to do so in a way that would have produced a claimed invention. The Office posits only a single rationale as to why it would have allegedly been obvious to one skilled in the art to modify the tip of the catheter of the Reiley patent or that of the Kriesell publication by providing a "porous layer tip" as disclosed by the Moaddeb patent: "to be maneuvered more easily and safely into position with less patient trauma" (4/9/08 Office Action at page 3). However, as clearly provided in the Moaddeb patent (and as demonstrated in Applicants' January 11, 2008 Reply), the ability of the catheter to be easily and safely maneuvered and to reduce the probability of "patient trauma" is not attributable to the "porous layer" disclosed in the Moaddeb patent, but rather to other features of the disclosed catheter, such as the "lubricious surface" conferred by the "hydrogel layer" (*see* Moaddeb patent at col. 4, lines 1-6). In fact, the purpose of the "porous layer" is to improve a feature that is ***unique to ablation catheters*** (*i.e.*, the dissipation of heat during ablation; *see* Moaddeb patent at col. 5, lines 9-10) and is ***irrelevant*** to delivery systems such as the device disclosed in the Reiley patent or the device disclosed in the Kriesell publication. Thus, one skilled in the art would

not modify the Reiley patent or the Kriesell publication by including a "porous layer" having the materials or characteristics as taught by the Moaddeb patent either to allow a catheter "to be maneuvered more easily and safely into position with less patient trauma", as proposed by the Office, or for any other reason.

The Office posits no other evidence or reasoning as to why those of ordinary skill would have been motivated to combine the disclosures of the Reiley patent and the Kriesell publication with that of the Moaddeb patent. Absent evidence or reasoning based on objective factors demonstrating that the posited modifications of the cited references would have been ones that those of ordinary skill in the art actually would have been motivated to make, the rejection of claims 3-8 for alleged obviousness is improper and should be withdrawn. *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. June 28, 2007) (confirming that obviousness cannot be established based on a combination of references absent "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does") (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007)). *See also May 3, 2007 Memo from Margaret A. Focarino, Deputy Commissioner for Patent Operations, U.S. Patent Office* ("it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. ") (commenting on *KSR Int'l Co*, 127 S. Ct. 1727 (2007)).

Second, even if one skilled in the art would have been motivated to combine the cited references, the resulting combination would not result in any claimed invention. With respect to claim 3, the Office's contention regarding the alleged disclosure by the Moaddeb patent of a porous tip comprising polylactic acid is factually inaccurate. Claim 3 specifies that the high-porosity tip comprises polylactic acid. The only materials from which the "porous layer" of the Moaddeb patent is made are those which have "good electrical conductivity over at least a portion" (Moaddeb patent at col. 4, lines 35-38), preferably "equal to or exceeding that of platinum" (*Id.* at col. 4, lines 42-44). The Moaddeb patent does not list "polylactic acid" among the materials from which the "porous layer" may be formed. Furthermore, polylactic acid is not understood among those skilled in the art to have "good electrical conductivity", and therefore the Moaddeb patent may be said to teach away from the use of this material in forming the "porous layer". Accordingly, there is no teaching or suggestion

in the Moaddeb patent, or indeed any of the other cited references, as to the subject matter of claim 3, and in addition the Moaddeb patent may be said to teach away from such subject matter. Thus, the rejection of claim 3 is also improper and should be withdrawn. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974) (to establish a prima facie case of obviousness, all claim limitations must be taught or suggested by the prior art); *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983) (it is improper to combine references where the references teach away from their combination).

As for claims 4-7, there is no teaching or suggestion in the posited combination of references to provide a high-porosity tip that is coated with a non porous or semi-porous material (as recited in claim 4) such as ceramic polymer, metal, calcium phosphate, PLLA, titanium, or a biocompatible or resorbable material (as recited in claims 5-7) that controls the direction of the flow of composition from the high-porosity tip. Although the Moaddeb patent teaches that the "porous layer"[1] may be coated with a "lubricious" hydrogel layer that "allow[s] the electrode to be maneuvered more easily and safely into position with less patient trauma" and to "create[] a surface on the tip electrode to which coagulate will not stick" (Moaddeb patent at col. 4, lines 1-6), there is no evidence of record that the hydrogel layer controls the direction of flow of a composition from the "porous layer", and there is no teaching or suggestion to use the hydrogel layer with the "porous delivery tip" of the Kriesell publication or that doing so would control the direction of flow from the "porous delivery tip". Accordingly, the posited combination of references does not teach or suggest the subject matter of any of claims 4-7, and the rejection of these claims for alleged obviousness should be withdrawn. *In re Royka*, 490 F.2d 981.

With regard to claim 8 (as amended), none of the cited references teach or suggest a high-porosity tip that is biocompatible and resorbable. As shown above, there is no evidence that the "porous delivery tip" of the Kriesell publication has a porosity that falls within the presently claimed range of about 60-90%; likewise, there is no evidence that the tip of the Kriesell publication is both biocompatible and resorbable. The Moaddeb patent does not

[1] As the Office has acknowledged, Applicants have previously demonstrated (see January 11, 2008 Reply at paragraph bridging pages 5-6) the tip electrode 30 of the Moaddeb patent represents a "dead end," *i.e.*, it is a solid, non-porous piece of material that does not include structures necessary to permit the passage of material from an internal space within the catheter, and the "porous layer" is merely an electrically-conductive layer of material that is applied to the outer surface of the solid material comprising the tip electrode 30.

remedy the shortcomings of the Kriesell publication, at least in the sense that the cited reference does not teach or suggest *any* high-porosity tip, much less a high-porosity tip that is biocompatible and resorbable (*see* Applicants' January 11, 2008 Reply and footnote 1, *supra*). Accordingly, the posited combination of references does not teach or suggest the subject matter of claim 8, and the rejection of this claim is therefore inapposite. *In re Royka*, 490 F.2d 981.

For at least these reasons, Applicants respectfully submit that the rejection of claims 3-8 under § 103(a) are improper and should be withdrawn.

Conclusion

The Applicants submit that the foregoing represents a *bona fide* attempt to advance the present case to allowance, and that the application is now in condition therefor. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 215-568-3100.

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